Utah Department of Health

CLINICAL LABORATORY BULLETIN February 2009

Web page: http://health.utah.gov/lab/labimp

❖ INTRODUCING

NOTEWORTHY

✓ **Using cell counters for platelet counts in blood banks:** Research published in *Transfusion.*2007;47:1651-1657 indicated 5 different hematology analyzers tested were suitable to accurately count platelets in blood bank platelet packs. Researchers used the Cell-Dyn 4000 CD61 as the reference method in their study. Cell counters analyze platelets based on impedance, optics, immunologic technology, or a combination of the three. Researchers used the AcT 8, Advia 2120, Onyx, K4500, XT 2000i (Sysmex) and Cell-Dyn 4000 to count the platelets. Researchers also studied EDTA's effect on platelet counts and the dilution of platelet concentrates using the 5 analyzers. The authors recommend all hematology analyzers used to count platelets in platelet donor packs be validated for that purpose as well as for the platelets in whole blood for complete blood count (CBC) analysis.

✓ **How soon can lab tests be done following radiology procedures using contrast media?:** The answer in the December issue of CAP Today was "Waiting 24 to 48 hours would be optimum but is not always practical." So what is a lab to do? The article states fluorescein dye is reported to interfere with creatinine, cortisol and digoxin. Iodine can cause inaccurate results for bicarbonate, chloride and red blood cell morphology. One study showed a dose dependant increase in coagulation test results following Ioxaglate use. If patient testing cannot be postponed, indicate on the report a contrast media was used in radiology that may alter the lab's test results.

✓ **Transfusion with older blood may be problematic:** Researchers at Cooper University Hospital in Camden, NJ found patients receiving blood cells stored 29 days or more were twice as likely to acquire hospital related infections as patients getting newer blood. Infections in the 422 ICU patients studied from July 2003 to September 2006 included septicemia, pneumonia, urinary-tract, heart-valve, and "other". Researchers point out such infections were not caused by blood products infectious at the time of infusion, but as a result of blood products degraded by age affecting the patient's immune system.

✓ **Vaginal KOH preparations – to warm or not to warm?:** Lauren Roberts, MS, MT(ASCP) from the Clinical Laboratory Science Program at Arizona State University in Tempe, AZ answered that question in the December 2008 issue of MLO.

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Ms. Roberts stated that generally, warming KOH preps for vaginal samples is not necessary. Warming aids cellular debris clearing in skin and nail samples. Responding to whether the writer's lab should use KOH containing DMSO, again Ms Roberts said it was unnecessary. DMSO is useful for hair, skin and nails as it helps dissolve cellular debris without warming the preparation.

Ms. Roberts reminded testing personnel to include a saline slide with the KOH preparation for vaginal samples as KOH destroys *Trichomonas vaginalis* and clue cells.

✓ **When urinalysis and culture disagree:** Susan E Sharp, PhD, Director of Microbiology at Kaiser Permanente addressed this question in the November, 2008 MLO. The writer questioned positive nitrite and leukocytes in a urine with no growth on the MacConkey's and blood agar plates. The answer = maybe neither test result is wrong.

Dr. Sharp states other conditions can cause increased white blood cells in urine besides bacterial infections (urinary tract injury from calculous disease, stricture disease, neoplasm, interstitial cystitis or glomerulonephropathy). The patient may be on antibiotics which prevent pathogenic bacterial growth. Also some organisms cause increased WBCs that will not grow on traditional urine culture media (chlaymdia, mycoplasma or ureaplasma).

Urine nitrites can be falsely elevated by contamination, exposure to air, or phenazopyridine use. They can be falsely negative when the specific gravity or urobilinogen levels are elevated, there is a nitrate reductase-negative bacterial infection, pH is <6.0 or the patient is taking vitamin C.

✓ **Public Health Laboratories have a new molecular influenza test:** The Center for Disease Control and Prevention (CDC) and Applied Biosystems developed a test kit that was approved by FDA the end of September, 2008. The kit identifies Influenza A and B as well as sub-typing for H1, H3 and the H5 strain tied to "bird flu". CDC began distributing the primers and probes to state public health labs in January. The kit can be used on nasal or naso-pharyngeal swabs, **NOT** on throat swabs. The Utah Public Health Laboratories is currently using a molecular test through APHL (Association of Public Health Laboratories). The advantage of the CDC kit is standardized reagents so results can be comparable throughout the USA. UPHL is currently validating the new method. Use of the new kit will depend on funding.

✓ **Estimating VLDL in patients with high triglyceride values:** Greg Miller, PhD, Professor of Pathology for the Virginia Commonwealth University stated in the July 2008 issue of CAP Today that very-low-density lipoprotein (VLDL) should not be estimated when the patient's triglyceride level exceeds 400 mg/dL (4.5 mmol/L). Triglycerides between 200 and 300 mg/dL give less reliable results using the triglycerides/5 formula for calculating VLDL. The problem with high triglycerides is the sample may contain chylomicrons or unusual lipoproteins that make the Friedewald equation inaccurate.

✓ **Handling and storing sweat chloride specimens:** Researchers from the University of Texas Southwestern Medical Center and Children's Medical Center of Dallas conducted experiments with simulated sweat chloride specimens to determine how stable samples are after collection, and the actual length of time necessary to reweigh filter papers once the specimen is collected. Samples were prepared at 75, 100, 175 and 250 µL and added to weighed filter paper. The papers were placed in vials, stored in 100 mL plastic screw-capped urine collection containers and then tightly closed in a plastic sample transport bag. The samples were stored at room temperature or refrigerated and reweighed at 1, 4, 8, 24, 48 and

72 hrs. Samples at both storage temperatures were analyzed for chloride at 0, 8, 24, 48 & 72 hrs.

Results showed samples in tightly sealed vials are stable for up to 8 hours at room temperature before they must be reweighed. However heat (samples transported in "hot" cars) affected the chloride results as the filter paper weight was lowered even after only one hour. Likewise, refrigeration before reweighing the paper results in altered chloride results.

Samples can be collected off-site from the testing laboratory. But if the transport conditions will be in extreme heat or cold, the samples will need to be reweighed at the collection point before transport to the reference lab.

✓ **New Joint Commission standard for hospital coagulation clinics:** By January 2009 Joint Commission accredited hospitals were to have implemented a patient safety requirement to reduce the likelihood of patient harm associated with the use of anticoagulation therapy. Mark Wurster, MD from Ohio State University College of Medicine suggested several points to consider when planning your program in the May 2008 issue of CAP Today.

1. Make sure your patient has a baseline coagulation study before beginning warfarin therapy.

2. Keep a detailed patient history and update it whenever the patient has a prothrombin time (PT) test (warfarin interacts with 650 medications). Ask about any new symptoms, any medications (including herbal supplements), dietary changes, and anything else they should report (illness, change in activity, other disease diagnosis, etc.).

3. Give the patient written instructions on how and when to take their medication and when to come back for a blood test.

4. Newer generation point-of-care PT testing instruments have interfaces that can be adapted to your computer system. Keep an electronic record with complete patient progress notes.

5. There are at least 300 PT device / reagent combinations. Test results seldom compare between methods. In fact, the difference (in single digit measurements) can be up to 100% coefficient of variation. Dr. Wurster's advice is to pick a monitoring method and stay with it.

✓ **SOP:** Standard operating procedures (SOP) are the hallmark of a great lab. In fact, the more 4 inch binders you have on the shelf, the better quality results you produce – right? Answer: "Do employees read them? Do they use them? Do they understand them?" Do we put every conceivable piece of information into our procedures until the intent is lost? Lucia M. Berte, MA, MT(ASCP), SBB, DLM, etc. President of *Laboratories Made Better! PC* had some suggestions in the November 2008 issue of Lab Medicine. SOP have 3 separate parts:

Policy = stated intent.
Process = sequence of activities
Procedure = stepwise instructions

Ms. Berte suggests you aim for strength, flexibility and balance in the 3 components. She further proposes using the 12 Quality System Essentials to make the testing work flow no matter the test, lab size, or lab location.

"Most laboratories are unbalanced because they focus on acquiring the latest greatest technology as a means to solve problems, rather than understanding, documenting, and improving key laboratory processes." Laboratories are unbalanced when they focus on preparing for inspections rather than preparing their processes to deliver accurate, efficient results to customers timely.

You may contact Ms. Berte at Imberte@LaboratoriesMadeBetter.com for additional information.

☆ Feature ☆

SAFE PRACTICES FOR WORKING WITH SUSPECTED BACTERIAL SELECT AGENTS

Safety Reminder: When working with cultures suspected of containing *Francisella* or *Brucella*, ALL activities involving manipulations of cultures MUST be performed using BSL-3 conditions per the Centers for Disease Control and Prevention (see table on next page).

Following the CAP LPS exercise in October 2007, a frequently asked question from Sentinel laboratories was: "Sentinel laboratories are not usually BSL-3 labs, how can we safely work to rule-out or refer select agents such as *Brucella* spp. and comply with the CDC safety requirements?"

Some key parts of the BMBL 5th edition (Bacterial Agents chapter, *Brucella* spp.) will help answer this question.

> BSL-2 practices, containment equipment (i.e. a Class II biosafety cabinet) and facilities are recommended for working with routine clinical specimens of human or animal origin. If you are working with cultures, isolates or products of conception, which potentially contain high concentrations of *Brucella*, then all manipulations of these materials should be performed in a BSL-2 laboratory using BSL-3 practices and personal protective equipment (PPE).
>
> What does that mean for your laboratory operations?
>
> **BSL-2 facilities using BSL-3 practices and PPE:**

BSL-2 facilities:	A laboratory containing a Class II biosafety cabinet (BSC).
BSL-3 practices:	→All manipulations of cultures, plates and potentially concentrated forms of the organism must be conducted within a BSC. →Any centrifugation performed outside of a BSC must be performed in a centrifuge equipped with either safety caps and/or sealed rotors. →Do not use automated systems as they are often inaccurate in identifying bacterial select agents and they pose an exposure risk to laboratorians due to the potential for producing aerosols. →Locate the BSC away from high traffic areas of the lab, not directly under HVAC ceiling vents, nor near a doorway, all of which can disrupt the protective air circulation of a BSC. →Laboratorians working with a BSC, and any staff assisting or working within 5 feet of the BSC during its operation, should wear BSL-3 appropriate PPE.
BSL-3 PPE:	→Disposable gloves that overlap and cover the cuffs of the closed front gown. →Disposable, closed front (no buttons, snaps or zippers on the front) gowns that, worn in conjunction with gloves,

completely covers the hands, wrists and arms of the wearer.
→Eye protection, such as safety glasses or a face shield.
→Respiratory protection such as an N-95 rated mask or respirator (if a respirator is used, the laboratorian must be previously "fit tested" with the type of respirator that he or she will use).

Following these guidelines will enable your staff to safely work with *Brucella* spp., *Francisella tularensis* and other bacterial select agents to rule-out or refer these organisms. These guidelines comply with the CDC and BMBL requirements and they should be followed whenever one of these select agents is suspected to be contained in a specimen, including when working with proficiency testing specimens from CAP or Utah Public Health Laboratories (UPHL). Please contact UPHL if you have questions or if you need assistance in location sources of appropriate PPE, such as disposable closed front gowns.

TABLE 3B. MICROBIOLOGY SAFETY

Agent	BSL-2		Specimen Exposure Risk	Recommended Precautions for Sentinel Laboratories	
	Specimen Handling	Culture Handling			
Bacillus anthracis	2	2	Blood, skin lesion exudates, CSF, pleural fluid, sputum and, rarely, urine and feces	BSL-2: Activities involving clinical material collection and diagnostic quantities of infectious cultures.	BSL-3: Activities with high potential for aerosol or droplet production.
Brucella spp. (1)	2	3	Blood, bone marrow, CSF, tissue, semen and occasionally urine.	BSL-2: Activities limited to collection, transport and plating of clinical material.	BSL-3: All activities involving manipulations of culture.
Clostridium botulinum (2)	2	2	Toxin may be present in food specimens, clinical material (serum, gastric and feces) and environmental samples (soil, surface water). **TOXIN IS EXTREMELY POISONOUS!**	BSL-2: Activities with known or potentially containing toxin must be handled in a BSC (Class II) with a lab coat, disposable gloves and a face shield (as needed).	BSL-3: Activities with high potential for aerosol or droplet production.
Francisella tularensis (3)	2	3	Skin lesion exudates, respiratory secretions, CSF, blood and urine. Tissues from infected animals and fluids from infected arthropods.	BSL-2: Activities limited to collection, transport and plating of clinical material.	BSL-3: All activities involving manipulations of culture.
Yersinia pestis (4)	2	2	Bubo fluid, blood, sputum, CSF, feces and urine.	BSL-2: Activities involving clinical material collection and diagnostic quantities of infectious cultures.	BSL-3: Activities with high potential for aerosol or droplet production.
Smallpox (5)	4	4	Lesion fluids or crust, respiratory secretions or tissue	BSL-4: Specimen collection and transport.	
VHF (6)	4	4	Blood, urine, respiratory and throat secretions, semen and tissue	BSL-4: Specimen collection and transport.	

1. Laboratory acquired brucellosis has occurred by "sniffing" cultures, aerosols generated by centrifugation, mouth pipetting, accidental parenteral inoculations, sprays into eyes, nose and mouth; and finally by direct contact with clinical specimens.
2. Exposure to toxin is the primary laboratory hazard since absorption can occur with direct contact with skin, eyes or mucous membranes, including the respiratory tract. The toxin can be neutralized by 0.1 M sodium hydroxide. *Clostridium botulinum* can be inactivated by 1:10 dilution of household bleach. Contact time is 20 mins. If material contains both toxin and organisms, the spill must be sequentially treated with bleach and sodium hydroxide for a total contact time of 40 minutes.
3. Laboratory acquired tularemia infection has been more commonly associated with cultures than with clinical materials/animals. Direct skin/mucous membrane contact with cultures, parenteral inoculation, ingestion, and aerosol exposure have resulted in infection.
4. Special care should be taken to avoid the generation of aerosols.
5. Ingestion, parenteral inoculation, and droplet or aerosol exposure of mucous membranes or broken skin with infectious fluids or tissues are the primary hazards to laboratorians.
6. Respiratory exposure to infectious aerosols, mucous membrane exposure to infectious droplets, and accidental parenteral inoculation are the primary hazards to laboratorians.

Kim Christensen, Microbiologist, Utah Public Health Laboratories
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"Opportunity is missed by most people because it is dressed in overalls and looks like work."

Thomas Edison

CLIA BITS

ADDITIONAL WAIVED TESTS:

° Abbott i-STAT Crea Cartridge for creatinine
° Abbott i-STAT G Cartridge for glucose
° Abbott i-STAT 6+ Cartridge for glucose, hematocrit, hemoglobin, sodium, urea, chloride and potassium
° Abbott i-STAT EC4+ Cartridge for glucose, hematocrit, hemoglobin, sodium and potassium
° Abbott i-STAT E3+ Cartridge for hematocrit, hemoglobin, sodium and potassium

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Most frequent Utah CLIA deficiencies in 2008

1. Lack of quality assurance activities
2. Failure to verify twice yearly accuracy of tests for which proficiency testing is not required
3. Expired reagents
4. Failure to document proficiency testing evaluations were reviewed to discover problems
5. Current director failed to date and sign procedures or changes / updates to procedures

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Notify CLIA of changes

Most changes to your laboratory's testing menu and demographics can be done with a letter or on the fee coupon you receive every two years. Some changes **must** be made on the CMS 116 form (CLIA Application for Certification).

CMS 116 (complete all 4 pages) required for:
Initial application
Survey update (sent to lab by state agency prior to recertification or validation survey)
Certificate type change (except to waiver)
Reinstate certificate after 6 month closure
Change in director (except Certificate of Waiver or Accreditation)

Equals
"1 trillion pins: 1 terrapin"

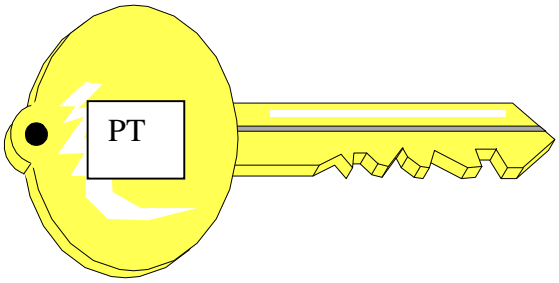
Quality Assessment Spotlight

Laboratory staff at the Obstetrics & Gynecology Clinic in Salt Lake City understands the quality assessment concept. During their recent survey they had documentation of patient specimen review for correct labeling and test record review to make certain VP Affirm specimens were tested within one hour of collection (pre-analytic). They documented quality control review including new lot number checks with external controls (analytic). And there was documentation of random chart review to check testing personnel were identified and reports matched the patient log.

Kudos Sheree Pollitz and staff

Ponderables:

Why is it that people say the "slept like a baby" when babies wake up like every two hours?



Proposed Changes to Cytology Proficiency Testing

- **Old**: annual testing with 4 chances to pass (score 90%). **New**: test every 2 years with 4 chances to pass (score 90%).

- **Old**: first two screens each year = 10 slides read in 2 hrs. Last two screens = 20 slides in 4 hrs. **New**: all four screens in the two year period = 20 slides to read in 4 hrs.

- **Old**: miss one high grade or cancer slide = event failure no matter the score. **New**: miss two high grade or cancer slides = event failure no matter the score.

Comments on the proposed changes can be sent to CMS until March 17, 2009. CMS and CDC will review the changes and propagate the final rule. A copy of the proposed rule is available at www.cms.hhs.gov/center/clinical.asp.

SAFETY

Alcohol Hand Gels

In 2006 a Michigan hospital nurse applied hand gel and reached to answer an electronic call system. The motion created static electricity and the alcohol in the gel on her hand ignited. Some key points on hand sanitizing gels were offered by Diane L. Davis, PhD in the November 2008 issue of Lab Medicine. They include:

- Wait 15 seconds after applying the gel before resuming your duties.
- Keep gel dispensers and gel bulk storage areas away from heat and electrical sources to minimize fire hazards.
- Make certain dispensers give the optimum amount of gel and are maintained to prevent blockage that would prevent the correct amount being dispensed.
- Understand gels do not kill all organisms. Read the product information. Spore forming bacteria (*Clostridium difficile, Clostridium* and Bacillus species); certain parasites (amoebic dysentery, *Giardia lamblia*, and *Cryptosporidium*); some viruses (norovirus, calicivirus, picornavirus and parvovirus) and prions may require traditional hand washing techniques to be effectively removed from the skin.

Use gels correctly and effectively to garner all their benefits.

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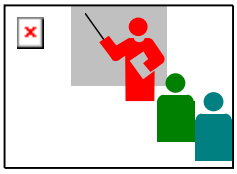
Re-using Syringes

Canada is experiencing at least three separate incidents of single use phlebotomy devices being used on multiple patients. In Manitoba a nurse was reusing Accu-Check single-use finger-stick blood collection devices which may have exposed as least 17 patients to bloodborne pathogens. In Alberta as many as

2,700 dental and endoscopy patients may have been exposed to hepatitis and HIV by reusing syringes at a health clinic. And finally there is a lawsuit in Saskatchewan regarding hospital employees reusing needles and syringes to inject intravenous bags with medications. Bottom line – it can't be worth the cost of even one case of hepatitis or HIV to reuse a syringe or other blood collection device meant for single use.

CONTINUING EDUCATION



Packaging & Shipping Workshop

The workshop will be held at the Utah Public Health Laboratories March 26, 2009. The course is presented by Patricia Payne, Ph.D., MT(ASCP) and will meet regulatory requirements for biennial certification.

Enroll now http://www.nltn.org/009-09.htm

Limited to 25 participants.

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Clinical and Laboratory Standards Institute (CLSI)

User Protocol for Evaluation of Qualitative Test Performance EP12-A2.

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APHL Training Opportunities

Check the website www.aphl.org for teleconferences, hands-on training, web casts and on-demand training.

Understanding Our Universe

"The universe is a big place, perhaps the biggest."

Kilgore Trout